Judge Marc L. Barreca
Chapter 11
Hearing date: January 7, 2015, 1:30 p.m.
Response date: December 31, 2014

UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

In Re: NATURAL MOLECULAR TESTING CORPORATION, Debtor.	No. 13-19298-MLB Chapter 11
NATURAL MOLECULAR TESTING CORPORATION, a Washington corporation, Plaintiff, v. CENTERS FOR MEDICARE & MEDICAID SERVICES, *et al*., Defendants.	No. 13-01635-MLB **DEFENDANTS' MOTION FOR DECLARATION OF INAPPLICABILITY OF AUTOMATIC STAY, OR, IN THE ALTERNATIVE, FOR RELIEF FROM STAY FOR AGENCY REVIEW OF MEDICARE REIMBURSEMENT DISPUTE**

Pursuant to the colloquy with the Court at the November 14, 2014 hearing, Defendants respectfully move for a declaration that the automatic stay of 11 U.S.C. § 362(a) does not apply

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to the Centers for Medicare & Medicaid Services' ("CMS") ongoing review of Natural Molecular Testing Corporation's ("NMTC") claims for Medicare reimbursement. The review process is simply a determination of whether and to what extent CMS has claims against NMTC. Neither the review nor the findings letters include or constitute a demand for payment. Accordingly, neither violate the automatic stay. Furthermore, these acts are not violations of the automatic stay because they are taken pursuant to HHS's role as a regulatory and police power in protection of the public welfare. In the alternative, should the Court determine that the automatic stay does apply to CMS's claims review, Defendants move for relief from stay retroactive to the petition date for the cause described herein.

I. BACKGROUND

A. The Claims Review and Overpayment Determination Process and Notifications

NMTC is a laboratory-based company that claims to use molecular diagnostics and molecular biology to diagnose and monitor disease, detect risks, and evaluate therapies for individual patients. *See* (Dkt. #55) (Amended Complaint) ("Am. Cmpl.") at ¶ 3.5. From 2010 until 2013, NMTC was a voluntary participant in the Medicare program that submitted at least 170,000 claims for reimbursement to CMS. *See* (Dkt. #73-1) (Declaration of Janet Freeman in Support of Motion to Stay Discovery) at ¶ 8; *see also* (Dkt. #55) at ¶¶ 3.2; 3.33; 3.34.

On April 25, 2013, AdvanceMed, a Medicare Zone Program Integrity Contractor ("ZPIC"), issued NMTC a notice advising that a payment suspension took effect on April 24, 2013. *Id*. at ¶¶ 3.40-3.41. The payment suspension was based, in part, on information AdvanceMed had obtained during a 2012 on-site review, in addition to "information provided by

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the ordering physicians and a subsequent analysis of [NMTC's] billings." *See* (Dkt. #67) ("Motion for Judgment") at Attachment A, 1-2. AdvanceMed also notified NMTC that the payment suspension involved "credible allegations of fraud." *Id.* at 2; Am. Cmpl. ¶ 3.41.

When a payment suspension is based upon credible allegations of fraud, "subsequent action must be taken by CMS or the Medicare contractor to make a determination as to whether an overpayment exists." 42 C.F.R. § 405.372(c)(2)(i). Before the payment suspension, AdvanceMed began a review of NMTC's claims for Medicare reimbursement since January 1, 2011 to determine if there had been overpayments for services that were not "reasonable and necessary" as required by law. 42 C.F.R. § 405.372(c)(2)(i); 42 U.S.C. § 1395y(a)(1)(A).

On August 21, 2014, AdvanceMed issued to NMTC an overpayment findings determination for Universe 1 of NMTC's claims. It states in bold on the first page of the letter "**This is not a demand letter**." *See* Declaration of Janet Freeman, Exhibit A. On August 28, 2014, Noridian Healthcare Solutions issued to NMTC an initial determination of overpayment based upon AdvanceMed's findings. *Id*., Exhibit B. It acknowledges that NMTC has filed for bankruptcy and immediately notes "Nothing in this letter should be considered as a demand for payment" but notes "any payments may be subject to recoupment, as applicable, to recover the overpayments." *Id.* Likewise, AdvanceMed issued an overpayment findings determination for Universe 2 on November 26, 2014. *Id*., Exhibit C. It contains the same language regarding it not being a demand for payment. *Id*.

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B. NMTC's Medicare Billing Practices Have an Impact on Public Welfare

The overpayment determinations by AdvanceMed demonstrate that not only has there been significant harm to the Medicare Trust Fund as a result of NMTC's practices, but also harm to patients. For instance, in the findings supporting Universe #1 and Universe #2, AdvanceMed noted that the high number of genetic tests supposedly ordered by individual physicians raised questions regarding whether such wide-scale human specimen testing was actually medically necessary, or was instead the result of unlawful kickback schemes that incentivized doctors to order testing regardless of medical necessity. *See* Freeman Dec. at Ex. A, 4 ("This type of volume from a single referring provider raises concerns about kickbacks and services which may not be medically necessary"); Ex. C, 4 ("Some physicians were responsible for referring very large numbers of beneficiaries for this testing, leading to concerns about kickbacks and services which may not be medically necessary").

Indeed, the suspicion of a kickback scheme has been corroborated through a criminal investigation. The evidentiary basis for the criminal investigation was previously set forth in a sealed search warrant affidavit, which was only recently unsealed and, therefore, can now be shared with this Court. *See* Freeman Dec., Exhibit D (Affidavit of Scott Schneckenberger, HHS-OIG). Pages 2 to 14 of the affidavit detail a payment scheme in which doctors were provided what the government contends were improper payments designed to induce them to order buccal swabs taken from their patients for testing by NMTC. *Id.* The resulting numbers of tests ordered also suggests that this unlawful incentive program led doctors to order tests that were not medically necessary for their patients. *See, e.g., id.* at ¶ 28 (doctor ordered genetic testing for over 200 patients in four months); ¶ 39 (doctor ordered genetic tests for 240 patients in five

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months). Further, a number of beneficiaries complained to HHS about NMTC's testing, indicating that they did not understand the need for the test and/or believed the test was unnecessary. *See* Exhibit A (overpayment findings letter Universe 1) at 20-21 (including a patient in hospice who unquestionably could not benefit from the testing).

The performance of unnecessary and inappropriate genetic testing on hundreds of Medicare beneficiaries not only harms the financial integrity of the Medicare Program (and its ability to appropriately serve patients with legitimate medical needs), it also subjects patients to unnecessary invasion of their bodies and affronts their dignity. Thus, while the harm of NMTC's scheme is financially enormous, there is decidedly also a patient welfare component.

C. This Proceeding and the Request for this Motion

NTMC filed its petition for bankruptcy on October 21, 2013, and filed this adversary proceeding against CMS on December 20, 2013. On March 31, 2014, HHS filed Claim 83, which encompassed any amounts that may become due as a result a Medicare program integrity review of NMTC's billed claims. The Court ordered the adversary proceeding stayed on November 21, 2014, in deference to CMS's primary jurisdiction to make overpayment determinations through that claims review process. At a hearing held November 14, 2014, after rejecting the trustee's claim that CMS's payment suspension violated the automatic stay, the Court indicated that there may be a need for "either a protective comfort order of relief from stay or some other determination that the stay doesn't apply" for CMS's claims review process. This motion is brought pursuant to that request.

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II. ARGUMENT

A. The Automatic Stay Does Not Bar CMS From Determining What Claim it May Have Against NMTC

The automatic stay has no application to CMS's ongoing review of available records to determine if NMTC received or has demanded overpayments for its Medicare reimbursement claims. CMS, "like any other creditor, is entitled to determine whether it possesses a valid claim against a debtor." *In re Carlson*, 126 F.3d 915, 924 (7th Cir. 1997) (Automatic stay does not apply to actions by IRS to determine amount of a tax deficiency). Through its claims review, CMS is not attempting to collect a claim against the debtor's estate in violation of the automatic stay. Indeed, the overpayment determination letters CMS has issued so far to NMTC explicitly deny such a purpose. *See* Freeman Dec. at Exhibits A-C. Instead, CMS is simply determining the amount it can claim in NMTC's bankruptcy proceeding.

Furthermore, CMS's claims review is a necessary precursor to exercising the agency's recoupment rights. Recoupment does not violate the automatic stay because it does not operate as an independent claim; rather, it acts more as a compulsory counterclaim or affirmative defense to a debtor's demand for payment arising out of the same transaction or occurrence as the recouped funds. *Newbery Corp. v. Fireman's Fund Ins. Co.* 95 F.3d 1392, 1399-1400 (9th Cir. 1996) ("There is no element of preference here or of an independent claim to be set off, but merely an arrival at a just and proper liability on the main issue"). Thus, the Ninth Circuit has unmistakably held that CMS's recoupment of overpayment amounts from other funds due under the same provider agreement is <u>not</u> a violation of the automatic stay. *In re TLC Hosp.*, 224 F. 3d 1008, 1013-14 (9th Cir. 2000); *see also In re Fischbach*, 464 B.R. 258, 267-68 (Bankr. D.S.C. 2012) (Recoupment by CMS permissible pursuant to Medicare Part B supplier agreements), *aff'd*

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2013 WL 1194850 (D.S.C. March 22, 2013). Given that CMS has the right to recoup, it must also have the right to determine what amount is subject to recoupment through its claims review. Thus, to hold that the automatic stay bars the claims review process would effectively strip CMS of its recoupment defense against NMTC's demands for payment, in flat contradiction to well-settled law.

B. CMS's Claims Review Process Falls Within the Police and Regulatory Power Exception

The filing of a bankruptcy petition does not stay "the commencement or continuation of an action or proceeding by a governmental unit . . . to enforce such governmental unit's . . . police or regulatory power." 11 U.S.C. § 362(b)(4). An agency action fits within this exception if it meets either one of two related tests: the pecuniary purpose test or the public policy test. *See In re Universal Life Church Inc.*, 128 F.3d 1294, 1297 (9th Cir. 1997) (citing *NLRB v. Continental Hagen Corp.*, 932 F.2d 828, 833 (9th Cir. 1991)). *See also Lockyer v. Mirant Corp.*, 398 F.3d 1098, 1108–09 (9th Cir. 2005). Under the pecuniary purpose test, the question is whether the agency action "relates primarily to the protection of the government's pecuniary interest in the debtor's property or to matters of public safety and welfare." *Universal Life Church*, 128 F.3d at 1297. If the action "is pursued solely to advance a pecuniary interest," the regulatory power exception does not apply. *Id.* If, however, the action "seeks to protect public safety and welfare," the automatic stay does not apply. *Lockyer*, 398 F.3d at 1109. Under the public purpose test, "the court determines whether the government seeks to 'effectuate public policy' or to adjudicate 'private rights.'" *Id.* (quoting *Cont'l Hagen Corp.*, 932 F.2d at 833).

CMS's claims review process meets either version of the test. The Medicare Program is of vital importance to the welfare of millions of Americans who depend on the health services it

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provides. To ensure limited public funds are directed to those with the most immediate and serious needs, services reimbursed by Medicare must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). The Medicare program could not function without regulatory tools like payment suspension and program integrity claims review, which are essential to prevent and correct abusive billing that is not "reasonable and necessary." The harm caused by violating or disregarding the "reasonable and necessary" test is not just financial – a test that is not reasonable or necessary for patient health is a test that a patient should not have had to undergo. *See* Section I.B., *supra*. In addition to the physical act of removing DNA specimens from a patient's mouth, needless medical tests also affect patients' dignity and faith in the medical system. This is unquestionably an issue of public welfare worth protecting.

CMS's claims review also serves the fundamental public policy of protecting the integrity of Medicare. The police and regulatory power exception allows the government to pursue a False Claims Act suit up to judgment in order to *remedy* fraud. *In re Universal Life*, 128 F. 3d at 1298. As such, it surely also allows CMS to conduct an internal claims review to *determine* what damage a potentially fraudulent supplier may have wrought. If administrative tools like payment suspension and the resulting claims review were barred by the automatic stay, "Congress's desire to protect the integrity of the Medicare program could be completely frustrated." *In re The Orthotic Ctr.*, 193 B.R. 832, 835 (N.D. Ohio 1996). As such, the claims review process clearly fall within the police and regulatory power exception to the automatic stay. *Id*. ("The policy behind the police or regulatory exception to the automatic stay is to prevent the bankruptcy court from becoming a haven for wrongdoers.").

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C. Even if the Automatic Stay Applies, the Court Should Lift the Stay for Cause to Allow CMS to Liquidate its Claim

Even if the Court determines that the stay applies to CMS's claims review, CMS is entitled to relief from the stay at least to issue its initial determination of overpayment. Upon request of a party in interest, the court "shall" grant relief from stay "for cause." 11 U.S.C. § 362(d)(1). Cause exists (1) where the interests of judicial economy would be served, *Packerland Packing Co. v. Griffith Brokerage Co.* (*In re Kemble*), 776 F.2d 802, 807 (9th Cir. 1985), (2) where the debtor would otherwise be able to avoid unfavorable results, *see In re Goldstein*, 5 Fed. Appx. 757, 760 (9th Cir. 2001), and (3) where "a clear congressional policy exists" to have a dispute determined in another forum in the first instance, *see In re Castlerock Properties*, 781 F.2d 159, 163 (9th Cir. 1986) (terminating the stay in deference to a state court proceeding that was "about to take place involving the very same issues"). Here, cause exists lift the stay on each of these grounds.

1. Cause Exists to Lift the Stay in the Interests of Judicial Economy

As this Court has already held in deferring to the agency's administrative process, this is a complex case that "involves reimbursement issues that are directly affected by the application of the complex Medicare regulatory scheme," which, in turn, "involves interpretive issues that require [CMS's] specialized knowledge and expertise." *See* (Dkt. #168) (Oct. 27, 2014 Hearing Trans.) at 6:3-8. This court also recognized the "need for uniformity of administration [of the Medicare regulatory scheme]." *Id.* at 6:8-10. Judicial economy is clearly best served when agency expertise can be employed since CMS is in the best position to determine overpayments

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in the first instance. *Cf. Tassy v. Brunswick Hosp. Ctr., Inc.*, 296 F.3d 65, 75 (2d Cir. 2002) (Walker, J., dissenting) (also noting that "considerations of judicial economy overlap to a certain extent with those of agency expertise").

Moreover, lifting the stay to allow CMS to make the overpayment determination also promotes judicial economy because it reinforces, and remains consistent with, this Court's previous ruling to defer to the agency's primary jurisdiction. In order to allow the agency to continue its administrative process and make initial determinations, as this Court has already required, the agency's determinations themselves must be permitted in spite of the automatic stay. To hold otherwise would: (1) completely undermine this Court's earlier deferral ruling because the agency would be unable to make the very determinations this court so permitted; and (2) waste the resources of this Court (by nullifying the judicial resources spent on the deferral ruling) and of the agency (as substantial determinations have already been made and some determinations are ongoing). Accordingly, cause exists to lift the automatic stay in the interest of judicial economy.

2. Cause Exists to Lift the Stay Because the Stay Cannot be Used to Avoid Unfavorable Results

As discussed above, because NMTC was suspended from payments on the basis of credible allegations of fraud, CMS is required to make this initial determination. *See* 42 C.F.R. § 405.372(c)(2)(i) ("If a suspension of payment is based upon credible allegations of fraud in accordance with § 405.371(a)(2), subsequent action must be taken by CMS or the Medicare contractor to make a determination as to whether an overpayment exists."). To prohibit CMS from making these determinations, which, to date, have resulted in substantial overpayments, would allow NMTC to use the automatic stay impermissibly as a shield to avoid potentially

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unfavorable results triggered by credible allegations of fraud. *See, e.g., Easley v. Pettibone Mich. Corp.*, 990 F.2d 905, 911 (6th Cir. 1993) (suggesting that the stay does not apply "where the debtor is attempting to use the stay unfairly as a shield to avoid an unfavorable result").

3. Cause Exists to Lift the Stay in the Interest of the Clear Congressional Mandate that the Agency Make the Initial Determination

This Court should also lift the stay because Congress has mandated the initial adjudication of these reimbursement disputes by CMS. *See In re Castlerock*, 781 F.2d at 163. The Medicare Act provides the sole avenue for judicial review of a Medicare reimbursement dispute, and that avenue arises only after a "final" administrative decision (of which the initial payment determination is a part). Although this Court has declined to find that these statutory provisions limit its jurisdiction, it has recognized that deferral to the agency is warranted for initial determination of reimbursement amounts pursuant to its expertise in the complex arena of Medicare rules and regulations. *See* Dkt. #175 (granting deferral). This ruling is consistent with Congress's clear mandate that CMS make the initial determination on reimbursement disputes. Specifically, 42 U.S.C. § 1395ff(b)(1)(A) provides: "any individual dissatisfied . . . shall be entitled to . . . judicial review of the Secretary's final decision after such hearing as is provided in section 205(g) [42 U.S.C. § 405(g)] of this title." In turn, 42 U.S.C. § 405(g) provides for review of the Secretary's decision by filing a civil action within sixty days after the Secretary's final decision notice. And 42 U.S.C. § 405(h) makes clear that section 405(g) is the exclusive vehicle for a court's jurisdiction. Therefore, as the Supreme Court has held, a Medicare claimant's access to the courts arises only after the presentment of a claim to the Secretary and a channeling of "all aspects" of that claim through the agency's administrative process. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 12-13 (2000). Accordingly, the clear

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congressional mandate for the agency to make at least the initial determination for any reimbursement dispute provides cause to lift the stay.

III. CONCLUSION

For the foregoing reasons, Defendants move that the Court declare the automatic stay inapplicable to CMS's claims review process or, in the alternative, lift the automatic stay retroactive to the petition date.

DATED this 2nd day of December, 2014.

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